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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,965	07/28/2003	Manfred Keller	BHE 3.0-109 (CONT)	6183
27614	7590	11/04/2004	EXAMINER	
RALPH W. SELITTO, JR. C/O MCCARTER & ENGLISH, LLP GATEWAY CENTER FOUR 100 MULBERRY STREET NEWARK, NJ 07102			HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,965

Applicant(s)

KELLER ET AL.

Examiner

Mina Haghghatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt is acknowledged of preliminary amendments filed 07/28/03. Accordingly claims 1-21 are cancelled and new claims 22-61 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,645,466 in view of Bauer (WO 9915182).

Here, claims 1-15 of U.S. Patent No. 6,645,466 recite a dry powder formulation for inhalation in the form of an ordered mixture, comprising an active agent, inactive carrier particles and magnesium stearate. Dependent claims also recite a concentration range for magnesium stearate and the active agent, as well as the type of active agents. Bauer teaches formulations in a dry powder form comprising formoterol and budesonide with suitable carrier and diluents. Bauer discloses that the finely divided active

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ingredients may be in the form of an ordered mixture with acceptable diluents and carriers, which are coarse particles. The ordered mixture is prepared by mixing and blending of the active agents, the carrier and diluent particles and stored in and delivered by Turbuhaler (a trademark of Astra, which is multidose inhaler). Therefore, it would have been obvious to modify the formulations claimed in U.S. Patent No. 6,645,466 by implementing the method of preparing the powder formulations, the multidose inhaler device and the combination of active agents, well known in the art and taught by Bauer with the reasonable expectations of successfully preparing and dispensing a powder formulation comprising one or more active agents, suitable diluents and carrier particles for better treatment and inhalation methods.

Claims 44-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,645,466 in view of Keller et al (6,182,655).

Here, claims 1-15 of U.S. Patent No. 6,645,466 recite a dry powder formulation for inhalation in the form of an ordered mixture, comprising an active agent, inactive carrier particles and magnesium stearate. Dependent claims also recite a concentration range for magnesium stearate and the active agent, as well as the type of active agents. Keller et al (6,182,655) teaches an inhaler for multiple dosed administration of a dry powder comprising means for delivering metered doses of the active agent for inhalation. Therefore, it would have been obvious to modify the formulations claimed in U.S. Patent No. 6,645,466 by implementing a multidose inhaler device as taught by

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Keller et al with the reasonable expectations of successfully storing and dispensing a powder formulation comprising one or more active agents, suitable diluents and carrier particles for better inhalation methods.

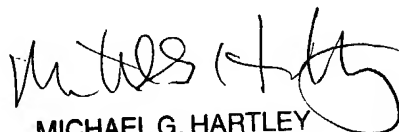
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
October 28, 2004



MICHAEL G. HARTLEY
PRIMARY EXAMINER